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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,019	02/09/2005	Masahiko Tanikawa	TANIKAWA1	7565

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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,019	TANIKAWA ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,11,12 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,11,12 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Applicant's request for continued examination received 2/6/08. Claims 1-6, 8, 11, 12, 19-24 are pending. No claims are withdrawn. Claims 7, 9, 10, 13-18 are cancelled. Claims 1, 11 and 20 have been amended. No claims are new.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/6/08 has been entered.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 1, 3, 4, 11, 12, 19-21 and 24 over Bohr et al. (U.S. Patent # 6060293) were considered but not found persuasive.

The Applicant argues that the inventive concept of the current application and Bohr et al. are completely different in scope and thus are not overlapping. While the Examiner appreciates the detailed theoretical description of the invention on page 5 and 6 of their response, the Examiner when considering the patentability of a method must consider the steps presented in the claims. In the instant claim 1 the method is for stabilizing a recombinant protein solution formulation by storing said solution under a magnetic field. Indeed this single step is performed by Bohr et al. as stated in the previous Office Action and repeated below.

The Applicant argues that the method of Bohr et al. does not and could not stabilize protein molecule. The Applicant argues that exposing the protein solution to the

electromagnetic field, specifically the microwaves as done by Bohr et al. would destabilize the solution. The Applicant submitted references by Zhong et al. and Milestone to support their argument. However these articles did not provide a nexus between the claims and the art applied. Certainly one of ordinary skill in the art would recognize that microwaves at high power would destabilize (cook or boil) protein solution formulations. The art is replete with teachings where microwave spectroscopy is used on proteins and leaves the protein intact as supported by Gordy et al. (PNAS, 1955). In a similar line of argument, one of ordinary skill in the art would recognize that using other electromagnetic radiation such as lasers could also cook, burn or simply disintegrate a protein molecule at high power. However the same skilled artisan would recognize that at low power these lasers serve as important instruments that study a protein solution formulation and leave said protein intact. One example would be Raman spectroscopy that frequently uses lasers to gain valuable structural information on a protein while leaving it intact as supported by Sharma et al. (JBC, 1988).

Indeed Bohr et al. is not silent to how their invention stabilize proteins in a formulation. They state that their magnetic fields stabilize the protein in solution by inducing the appropriate 3D folding (col 19, lines 45-50) that stabilizes the protein in its physiologically active folded state (col 9, lines 30-35). Therefore the rejection stands and is repeated below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 11, 12, 19-21 and 24 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bohr et al. (U.S. Patent # 6060293).

These claims are drawn to a method of stabilizing a recombinant protein solution formulation or recombinant protein-containing solution by storing these solutions under magnetic field lines. The recombinant protein is a physiologically active protein that is isolated and purified selected from the group such as an antibody, enzyme, cytokine and hormone.

Furthermore the claims 19-24 are drawn to stabilizing a composition of a protein in a pharmaceutically acceptable carrier such as water. The proteins for this composition consist of antibodies, enzymes, cytokines and hormones.

Bohr et al. teach a method for stabilizing a recombinant protein solution formulation and solution that contains a recombinant proteins, antibodies as well as enzymes, peptides, and polypeptides under magnetic field lines (see Abstract and col 22, lines 60-65 and col 29, lines 42-51). These proteins are inherently physiologically active since they are used for therapeutic purposes (see Abstract). The method of Bohr et al. can be adapted to a fermentation system for bulk recombinant protein production to reduce the formation of inclusion bodies and their isolation and purification (col 20, lines 25-65 and col 2, lines 20-36). The proteins can be stored under magnetic field lines while in pharmaceutically acceptable carriers such as water (Example 5 and Example 1).

Therefore the reference continues to anticipate claims 1, 3, 4, 11, 12, 19-21 and 24.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) or 102(a) (b) (c) rejection of claims 1-6, 11, 12, 19-24 over Bohr et al., Plantanias et al. and Rosse et al. were considered but not found persuasive.

The Applicant argues that since the amendments of made to claim 1 and the adjoining arguments overcome the teachings of the primary reference of Bohr et al. as applied above that they in turn overcome the remaining rejections that use these references. However as detailed above the Examiner disagrees and believes that the rejections using Bohr et al. are proper and in the absence of arguments to the contrary this rejections stand for the amended claims and are repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11, 12, 19-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bohr et al as applied to claims 1, 3, 4, 11, 12, 19-21 and 24 above and in further view of rational below with support from Plantanias et al. (JCO, 1991) and further support from Rosse et al. (ASH, Hematology 2000).

While Bohr et al. does store a recombinant protein solution formulation and protein solutions in a pharmaceutically acceptable carrier he does not specifically teach

the storage of recombinant hematopoietic factors such as erythropoietin and granulocyte colony-stimulating factor. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Bohr et al. One of ordinary skill in the art would recognize that recombinant molecules such as recombinant erythropoietin (**EPO**) has been used as a therapeutic agent to treat anemia resulting from chronic renal failure and cancer chemotherapy (as supported by Platanias et al. see abstract) and sickle cell anemia (as supported by Rosse et al. page 8, col 1 paragraph 1 and page 13, col 1 paragraph 3). Since the method of Bohr et al. intends to treat numerous diseases by producing, isolating and stabilizing recombinant proteins by storing them under magnetic field lines, it would have been obvious to someone skilled in the art to produce and stabilized EPO with the method of Bohr et al. The motivation is provided by Bohr et al. who expressly desires to treat anemia and cancer (col 27, 43-59) with the proteins produced by their method. The reasonable expectation of success comes from the successful treatment of anemia with EPO.

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-6, 11, 12, 19-24 are not allowable.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 1-6, 8, 11, 12, 19-24 over Bohr et al. in view of Cohen et al. were considered but not found persuasive.

The Applicant was confused why other claims were included in the rejection of Bohr et al. in view of Cohen et al. when claim 8 is the only claim that is drawn to a syringe. The rejection is made over the entire reference of Bohr et al. in view of the entire reference of Cohen et al., not simply the cited passages. In this manner if Bohr et al. alone anticipated claims 1-6, 11, 12, 19-24. Certainly these remain obvious when Bohr et al. is combined with Cohen et al.

The Applicant argues that since the amendments of made to claim 1 and the adjoining arguments overcome the teachings of the primary reference of Bohr et al. as applied above that they in turn overcome the remaining rejections in combination with Cohen et al. However as detailed above the Examiner disagrees and believes that the rejections using Bohr et al. are proper and in the absence of arguments to the contrary this rejections stand for the amended claims and are repeated below.

Claims 1-6, 8, 11, 12, 19-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bohr et al. as applied to claim 1-6, 11, 12, 19-24 above and in further view of Cohen et al. (U.S. Patent # 3308809).

The description and rejection of claims 1-6, 11, 12, 19-24 are listed in the 35 U.S.C § 103(a) rejection above. Claim 8 further limits the method of claim 1 by storing the protein solution formulation in a pre-filled syringe.

While Bohr et al. teach applying his method of storing a protein solution formulation to apparatus such as a Fermentor (Bohr, col 20, lines 38-67) they do not teach an apparatus such as a syringe. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of

Cohen who teaches a syringe for storing blood specimens form humans in syringes. Since the method of Bohr et al. is for treating blood type diseases such as sickle cell anemia, hemophilia (Bohr col 27, lines 42-59) it would have been obvious to someone skilled in the art to store the protein solution of Bohr et al. in the syringe of Cohen since Bohr et al. intends to treat diseases with their method and syringes are an obvious tool for the administration of therapeutic agents into the body.

Therefore the references listed above renders obvious claims 1-6, 8, 11, 12, 19-24.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
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